



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Orville G. Kolterman, et al.

Serial No.: 09/889,330

International Application Filing Date: January  
14, 2000

For: **NOVEL EXENDIN  
FORMULATIONS AND METHODS OF  
ADMINISTRATION THEREOF**

Group Art Unit: 1614

Examiner: To be assigned

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Patent  
0306390027-1  
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**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In compliance with Applicants' duty under 37 CFR 1.56, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08A and copies are enclosed for the convenience of the Examiner. Applicants respectfully request that an initialed copy of the PTO/SB/08A be returned with the next Communication.

It is believed that no fee is due for this submission since it is being filed before the mailing of a first Office Action on the merits. If, however, any fee should become due or credit become payable during the pendency of this application, the Patent Office is authorized to charge or credit the same to Deposit Account 50-1273.

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August 20, 2002  
Date of Deposit

Laura Largey  
Laura Largey

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Respectfully submitted,

Kolterman et al.

Dated:

August 19, 2002

By:

Lisa M. McGeehan

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Reg. No. 41,185

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

### Complete if Known

Application Number 09/889,330  
Filing Date January 14, 2000  
First Named Inventor Young  
Art Unit 1614  
Examiner Name TBA  
Attorney Docket Number 030639.0027.UTL1

Sheet 1 of 4

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Publication Date MMDDYYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	5,424,286		06-13-1995	Eng	

### FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	†
		Country Code <sup>3</sup>	Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	AB	WO	97/46584	12-11-1997	Boehringer Mannheim GmbH	Cited in International Search Report (copy attached)	
	AC	WO	98/08871	03-05-1998	Novo Nordisk A/S		
	AD	WO	98/30231	07-16-1998	Amylin Pharmaceuticals, Inc.		
	AE	WO	99/07404	02-18-1999	Amylin Pharmaceuticals, Inc.		
	AF	WO	99/25727	05-27-1999	Amylin Pharmaceuticals, Inc.		
	AG	WO	99/25728	05-27-1999	Amylin Pharmaceuticals, Inc.		
	AH	WO	99/40788	08-19-1999	Amylin Pharmaceuticals, Inc.		
	AI	WO	99/43708	09-02-1999	Novo Nordisk A/S		

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Application Number	09/889,330
Filing Date	January 14, 2000
First Named Inventor	Young
Art Unit	1614
Examiner Name	TBA
Attorney Docket Number	030639.0027.UTL1

Sheet	3	of	4
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	GLP-1 Analogs," <u>Diabetes</u> , 45(Suppl. 2):152A (1996) [abstract 553]	
AU	O'HALLORAN et al., "Glucagon-like Peptide-1 (7-36)-NH <sub>2</sub> : a Physiological Inhibitor of Gastric Acid Secretion in Man," <u>J. Endocrinol.</u> , 126(1):169-73 (1990)	
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AW	RAUFMAN et al., "Exendin-3, a Novel Peptide from <i>Heloderma horridum</i> Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly Described Receptor on Dispersed Acini from Guinea Pig Pancreas," <u>J. Biol. Chem.</u> , 266(5):2897-902 (1991)	
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BC	THORENS, "Expression Cloning of the Pancreatic $\beta$ Cell Receptor for the Glucagon-like Peptide 1," <u>P. Natl. Acad. Sci. USA</u> , 89:8641-45 (1992)	
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BE	WANG et al., "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," <u>J. Clin. Invest.</u> , 95:417-21 (1995)	

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Art Unit	1614
Examiner Name	TBA
Attorney Docket Number	030639.0027.UTL1

Sheet	4	of	4
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BF	WETTERGREN et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <u>Digest. Dis. Sci.</u> , 38(4):665-73 (1993)
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*Complete if Known*

Application Number	09/889,330
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First Named Inventor	Young
Art Unit	1614
Examiner Name	TBA
Attorney Docket Number	030639.0027.UTL1

Sheet 2 of 4

**OTHER PRIOR ART: NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	AJ	BHAVSAR et al., "Inhibition of Gastric Emptying and of Food Intake Appear to be Independently Controlled in Rodents," 25 <sup>th</sup> Annual Meeting, November 11-16, 1995, San Diego, California, <u>Soc. Neurosci.</u> , 21:460 (Abstract) (188.8) (1995)	
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	AL	DANIEL et al., "Use of Glucagon in the Treatment of Acute Diverticulitis," <u>British Medical Journal</u> , 3:720-2 (1974)	
	AM	EISSELE et al., "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-Like Peptide-1 (GLP-1) Amide," <u>Life Sci.</u> , 55(8):629-34 (1994)	
	AN	ENG, "Prolonged Effect of Exendin-4 on Hyperglycemia of db/db Mice," <u>Diabetes</u> , 45(Supp 2):152A (abstract 554) (1996)	
	AO	ENG et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <u>J. Biol. Chem.</u> , 265(33):20259-62 (1990)	
	AP	ENG et al., "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," <u>J. Biol. Chem.</u> , 267(11):7402-5 (1992)	
	AQ	GLAUSER et al., "Intravenous Glucagon in the Management of Esophageal Food Obstruction," <u>J. Am. Coll. Emer. (JACEP)</u> , 8(6):228-231 (1979)	
	AR	GOKE et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting $\beta$ -Cells," <u>J. Biol. Chem.</u> , 268(26):19650-55 (1993)	
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	AT	MONTROSE-RAFIZADEH et al., "Structure-function Analysis of Exendin-4 /	

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